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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,235	03/17/2004	Elizabeth Dzeng	Stanford S03-060	5638
39843	7590	08/24/2007		
BELL & ASSOCIATES 416 FUNSTON ST., SUITE 100 SAN FRANCISCO, CA 94118			EXAMINER GIBSON, ROY DEAN	
			ART UNIT 3739	PAPER NUMBER
			MAIL DATE 08/24/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/803,235

Applicant(s)

DZENG ET AL.

Examiner

Roy D. Gibson

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 and 34-36 is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-31 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Formal Matters***

The allowably of clam 11 is withdrawn in light of newly found prior art as presented below, therefore, this Office action is non-final.

### ***Claim Objections***

Claim 33 is objected to because of the following informalities: the claim depends from cancelled claim 32. The examiner has assumed the claim should depend form claim 31. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-9, 13, 14 and 22-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lafontaine (5,868,735).

Lafontaine discloses the heat exchange system essentially as claimed (Figure 3, where the first elongated tubular body is 140, the second elongated tubular body is 144, the balloon or saccular body is 114 and the marker is 36, see Figure 3 and col. 3, line 30-col. 4, line 2 and col. 4, line 39-col. 5, line 15). The thermal exchange composition

can be a variety of coolants (col. 4, lines 39-43, including liquid saline, wherein a pump 118 is disclosed (col. 3, lines 45-47).

Further to claims 5-7, these claims recite intended use only without modifying the structure of the system, and the examiner maintains that the system is fully capable of inserting the catheter into, for example, the urethra for treating it or the prostate.

Further to claims 13-14, Lafontaine further discloses a third elongate tubular body (guidewire lumen 134) having a proximal end and a distal end, the third elongate tubular body disposed longitudinally within the second elongate tubular body, and wherein the balloon is sealably affixed to the outer surface of the first elongate tubular body and sealably affixed to the outer surface of the third elongate tubular body and further comprising a guidewire disposed longitudinally within the third elongate tubular body, the guidewire having a proximal end and a distal end (col. col. 3, lines 40-47).

Claims 1-10, 22, 23 and 25-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Buchholtz et al. (5,409,006). Buchholtz et al. disclose the heat exchange system essentially as claimed (Figure 3, where the first elongated tubular body is 29, the second elongated tubular body, the balloon or saccular body is 22 and the marker is M1 (col. 7, line 20-col. 8, line 4).

Further to claims 5-7, these claims recite intended use only without modifying the structure of the system, and the examiner maintains that the system is fully capable of inserting the catheter into, for example, the urethra for treating it or the prostate.

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Further to claim 10, Buchholtz et al. disclose an ultrasound transducer affixed to the system (Figure 1 and col. 3, line 59-col. 4, line 47).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine ('735) in view of Lafontaine (6,068,653).

Regarding claim 11, Lafontaine ('735) discloses all elements of the system except for the guide sheath fitted over at least a portion of the catheter (140). But, Lafontaine ('653) discloses "an outer catheter tube 68 defining a lumen 70 of sufficient dimensions for accepting the catheter tube 32, as shown in FIG. 4. The catheter tube 32 is disposed coaxially within the lumen 70 and is connected, at its proximal portion 34 to a manifold assembly 12, as shown in FIG. 1. The catheter tube 68 can be a guide catheter, or similar structure, and can be positioned adjacent the tissues prior to insertion of the catheter tube 32 into the lumen 70 (col. 10, lines 38-44).

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Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Lafontaine ('735) with a guide catheter or sheath, as taught by Lafontaine (6,068,653), to assist in positioning the catheter at the required location for treatment.

Further to claim 15, the examiner has assumed that the "digestible composition" is merely a lubricant affixed (placed as a coating) on the end of the guidewire to assist the patient in swallowing the guidewire. The examiner maintains that this addition of a "digestible composition" is well known in the art.

Regarding claims 16-21 which recite various cooling rates for a treated organ, the examiner maintains that it would have been obvious to a skillful artisan to adjust the cooling rates as required for the specific coolant selected and that these rates could be determined by routine experimentation. The examiner further maintains that system of Lafontaine ('735) is fully capable of achieving the claimed rates.

Claims 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. (5,716,386). Ward et al. disclose the method of altering the temperature of the myocardium essentially as claimed, except for the marker (assumed to be a radio-opaque marker and see Figures 14 and 16, col. 14, lines 22-61 and col. 15, lines 21-57). The examiner maintains that markers are well known in the art as demonstrated by the Lafontaine ('735) reference above.

***Allowable Subject Matter***

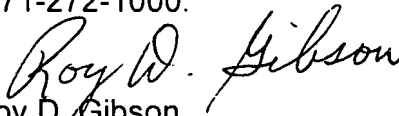
Claims 12 and 34-36 are allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Roy D. Gibson  
Primary Examiner  
Art Unit 3739

August 20, 2007